



## General

### Guideline Title

Management of menopausal symptoms.

### Bibliographic Source(s)

American College of Obstetricians and Gynecologists (ACOG). Management of menopausal symptoms. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2014 Jan. 15 p. (ACOG practice bulletin; no. 141). [112 references]

### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). Use of botanicals for management of menopausal symptoms. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2001 Jun. 11 p. (ACOG practice bulletin; no. 28). [56 references]

## Recommendations

### Major Recommendations

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of the "Major Recommendations" field.

The following recommendations and conclusions are based on good or consistent scientific evidence (Level A):

- Systemic hormone therapy (HT) with estrogen alone or in combination with progestin, is the most effective therapy for vasomotor symptoms related to menopause.
- Low-dose and ultra-low systemic doses of estrogen are associated with a better adverse effect profile than standard doses and may reduce vasomotor symptoms in some women.
- Given the variable response to HT and the associated risks, it is recommended that health care providers individualize care and treat women with the lowest effective dose for the shortest duration that is needed to relieve vasomotor symptoms.
- The risks of combined systemic HT include thromboembolic disease and breast cancer.
- Selective serotonin reuptake inhibitors (SSRIs), selective serotonin norepinephrine reuptake inhibitors (SSNRIs), clonidine, and the gabapentin are effective alternatives to HT for the treatment of vasomotor symptoms related to menopause.
- Estrogen therapy effectively alleviates atrophic vaginal symptoms related to menopause. Local therapy is advised for the treatment of women with only vaginal symptoms.
- Paroxetine is the only nonhormonal therapy that is approved by the U.S. Food and Drug Administration (FDA) for the treatment of vasomotor symptoms.
- The FDA approved ospemifene for treating moderate-to-severe dyspareunia in postmenopausal women.

The following conclusions are based on limited or inconsistent scientific evidence (Level B):

- Data do not support the use of progestin-only medications, testosterone, or compounded bioidentical hormones for the treatment of vasomotor symptoms.
- Data do not show that phytoestrogens, herbal supplements, and lifestyle modifications are efficacious for the treatment of vasomotor symptoms.
- Nonestrogen water-based or silicone-based vaginal lubricants and moisturizers may alleviate vaginal symptoms related to menopause.
- Common sense lifestyle solutions such as layering of clothing, maintaining a lower ambient temperature, and consuming cool drinks are reasonable measures for the management of vasomotor symptoms.

The following recommendation is based primarily on consensus and expert opinion (Level C):

- The decision to continue HT should be individualized and be based on a woman's symptoms and the risk–benefit ratio, regardless of age.

#### Definitions:

#### Grades of Evidence

I: Evidence obtained from at least one properly designed randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

#### Levels of Recommendation

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

## Clinical Algorithm(s)

None provided

## Scope

## Disease/Condition(s)

Menopausal symptoms

- Vasomotor
- Vaginal

## Guideline Category

Management

Treatment

# Clinical Specialty

Family Practice

Obstetrics and Gynecology

## Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

## Guideline Objective(s)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To provide evidence-based guidelines for the treatment of vasomotor and vaginal symptoms related to natural and surgical menopause

## Target Population

Women experiencing menopausal symptoms

## Interventions and Practices Considered

1. Systemic hormonal therapy (HT):
  - Estrogen therapy alone
  - Estrogen combination therapy with progestin
2. Nonhormonal medications:
  - Selective serotonin reuptake inhibitors (SSRIs) and selective serotonin-norepinephrine reuptake inhibitors (SSNRIs) (paroxetine)
  - Clonidine
  - Gabapentin
3. Estrogen agonists and estrogen antagonists (ospemifene)
4. Alternative techniques:
  - Common sense lifestyle solutions
  - Vaginal lubricants

Note: Interventions that were considered but not recommended include progestin-only medications, testosterone, or compounded bioidentical hormones; phytoestrogen, herbal remedies, vitamins, and lifestyle modifications.

## Major Outcomes Considered

- Adverse effects of hormonal therapy (HT)
- Efficacy of nonhormonal medications

## Methodology

### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 2000 and April 2013. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guide lines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician-gynecologists were used.

## Number of Source Documents

Not stated

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

Grades of Evidence

I: Evidence obtained from at least one properly designed randomized controlled trial

II-1: Evidence obtained from well-designed controlled trials without randomization

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

## Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

## Description of the Methods Used to Analyze the Evidence

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force. See the "Rating Scheme for the Strength of the Evidence" field.

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See the "Rating Scheme for the Strength of the Recommendations" field regarding Level C recommendations.

## Rating Scheme for the Strength of the Recommendations

### Levels of Recommendation

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

### Internal Peer Review

## Description of Method of Guideline Validation

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Improved management of menopausal symptoms

### Potential Harms

#### Hormone Therapy (HT)

- Although HT is well tolerated by most women, standard doses may cause adverse effects, such as breast tenderness, vaginal bleeding, bloating, and headaches.
- The risks of systemic combined HT include thromboembolic disease and breast cancer. The majority of trials that analyzed the safety of HT

have assessed preparations containing conjugated equine estrogen alone or in combination with medroxyprogesterone acetate. The Women's Health Initiative (WHI) study, a large randomized controlled trial (RCT) of healthy menopausal women aged 50 to 77 years, demonstrated a slightly increased risk of breast cancer, coronary heart disease, stroke, and venous thromboembolic events and a decreased risk of fractures and colon cancer after an average of 5 years of combined HT. Among women receiving estrogen only, there was an increased risk of thromboembolic events, but not an increased risk of cardiovascular events or breast cancer.

#### Clonidine

Common adverse effects reported were dry mouth, insomnia, and drowsiness.

#### Selective Serotonin Reuptake Inhibitors (SSRIs) and Selective Serotonin-Norepinephrine Reuptake Inhibitors (SSNRIs)

Reported adverse effects included nausea, dizziness, dry mouth, nervousness, constipation, somnolence, sweating, and sexual dysfunction, but these generally resolved with time or dose adjustment.

#### Gabapentin

Common adverse effects from gabapentin include dizziness, somnolence, and peripheral edema.

#### Estrogen Agonists and Estrogen Antagonists

Common adverse effects of ospemifene reported during clinical trials included hot flushes, vaginal discharge, muscle spasms, genital discharge, and excessive sweating.

## Qualifying Statements

### Qualifying Statements

The information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

## Implementation of the Guideline

### Description of Implementation Strategy

An implementation strategy was not provided.

### Implementation Tools

Audit Criteria/Indicators

Foreign Language Translations

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

## IOM Domain

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

American College of Obstetricians and Gynecologists (ACOG). Management of menopausal symptoms. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2014 Jan. 15 p. (ACOG practice bulletin; no. 141). [112 references]

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2001 Jun (revised 2014 Jan)

### Guideline Developer(s)

American College of Obstetricians and Gynecologists - Medical Specialty Society

### Source(s) of Funding

American College of Obstetricians and Gynecologists (ACOG)

### Guideline Committee

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

### Composition of Group That Authored the Guideline

American College of Obstetricians and Gynecologists (ACOG) committees are created or abolished and their overall function defined by the Executive Board. Appointments are made for one year, with the understanding that such appointment may be continued for a total of three years. The majority of committee members are Fellows, but Junior Fellows also are eligible for appointment. Some committees may have representatives from other organizations when this is particularly appropriate to committee activities. The president elect appoints committee members annually.

### Financial Disclosures/Conflicts of Interest

Not stated

## Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). Use of botanicals for management of menopausal symptoms. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2001 Jun. 11 p. (ACOG practice bulletin; no. 28). [56 references]

## Guideline Availability

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 933104, Atlanta, GA 31193-3104; telephone, 800-762-2264; e-mail: [sales@acog.org](mailto:sales@acog.org). The ACOG Bookstore is available online at the [ACOG Web site](#) .

## Availability of Companion Documents

A proposed performance measure is included in the original guideline document.

## Patient Resources

The following is available:

- Frequently asked questions: Menopause. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2013 Feb. 2 p. Electronic copies: Available in Portable Document Format (PDF) from the [American College of Obstetricians and Gynecologists \(ACOG\) Web site](#) . Copies are also available in [Spanish](#) .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## NGC Status

This NGC summary was completed by ECRI on September 22, 2004. The information was verified by the guideline developer on December 9, 2004. This NGC summary was updated by ECRI Institute on February 7, 2014.

## Copyright Statement

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

## Disclaimer

### NGC Disclaimer

The National Guideline Clearinghouse<sup>®</sup> (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the [NGC](#)



#### Inclusion Criteria.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.